

REMARKS

The subject invention is related to a method of skin tightening which includes generating broadband light and filtering that light to produce a spectrum having a wavelength band principally between 1050nm and 1850nm. The light is directed to the tissue through a cooled transmissive material which is placed in contact with the skin. The treatment period lasts between approximately 1.2 second to five seconds and heats a volume of the dermis at a depth between 1mm and 5mm to a treatment temperature at least 50°C while maintaining the upper regions of the dermis at a temperature below the treatment temperature.

Over the course of the prosecution of this application, Applicants have submitted a number of articles describing the use of the subject method to produce skin tightening in patients. (see Exhibits A to D to the Amendment filed on October 2, 2008). In addition, in response to the previous rejection and at the suggestion of the Examiner, Applicants submitted a declaration by Scott A. Davenport which described the genesis of the invention and how the development was not obvious based on the then current state of the art. The Examiner did not find the Davenport declaration persuasive for a number of reasons, including the fact that Mr. Davenport was an employee of the assignee Cutera and based on the belief that Mr. Davenport was not speaking as person with the knowledge of one ordinarily skilled in the art. Nonetheless, the Examiner still withdrew his prior rejection and issued a new rejection based on a different combination of prior art.

In support of Applicants' response to this new rejection, submitted herewith is the Declaration of Dr. Macrene Alexiades-Armenakas (Alexiades Declaration). Dr. Alexiades is a person highly skilled in the art of dermatology and skin tightening treatments. She is an assistant Clinical Professor at Yale University School of Medicine. She is a Fellow of both the American Academy of Dermatology and American Society for Laser Medicine and Surgery. Dr. Alexiades founded and directs a dermatology laser surgery and research center. She developed the first classification and grading scale for skin laxity and rhytides that has been utilized by several laser companies for quantitative grading of skin tightening devices. In addition, she ran the first "Skin Tightening Technologies" course at the American Academy of Laser Medicine and Sciences annual meeting.

As an independent consultant, Dr. Alexiades has performed studies associated with the FDA trials for virtually every new commercial product developed over the last ten years for skin tightening. In particular, she ran studies on the Thermacool system from Thermage, the Polaris, Galaxy, and ST Refirme systems from Syneron, the Accent system from Alma Lasers, the 1310 nm laser system from Candela, and the Miratone system by Primaeva.

Dr. Alexiades has also conducted studies on the Titan system from Cutera. The Titan system operates with the parameters of the method set forth in claim 15 and therefore Dr. Alexiades has specific experience using the claimed method in her studies.

Dr. Alexiades operates as an independent researcher and is not a paid consultant for any medical device company. She is compensated for the FDA studies she performs. She will be paid for the hours she has spent reviewing the prior art cited in the pending Office Action and for preparing her declaration. She owns no stock in Cutera and has no financial stake in Cutera or this application. As noted in paragraph 5 of her declaration, her views are “based on my extensive training in dermatology, my research experience evaluating various dermatology treatment protocols and my particular expertise in evaluating dermatology systems used for skin tightening.”

As noted above, Dr. Alexiades has worked with the Cutera’s Titan product performing the method of claim 15. Dr. Alexiades has observed “that the Titan device provides very consistent and very reproducible skin tightening effects. I am of the belief that a likely explanation for this performance is based on the selection of an optimal treatment wavelength range, which produces deeper heating and induces neoclastogenesis. At the time of my research with the Titan, I had not previously observed this consistent a skin tightening result with prior light based treatment systems, which I believe tended to deposit more energy in the upper regions of the skin and have only been shown to generate neocollagenesis.” (Alexiades Declaration, ¶9)

As will be discussed below, Dr. Alexiades’ Declaration supports Applicants’ position that none of the art cited in the pending Office Action, whether taken alone or in combination, render obvious the subject matter of the sole independent claim (claim 15) herein.

In the Office Action, the Examiner rejected claims 15 to 17, 22, 33, 42 and 43 as being unpatentable over Anderson (U.S. 6,120,497) in view of Altshuler (*042) and Altshuler (*780).

As will be discussed below, neither the primary references, nor any of the secondary references teach or suggest using a broadband spectrum treatment having a wavelength range principally between 1050nm and 1850nm. Further, none of the references, either alone or in combination render the subject matter of claim 15 obvious to one skilled in the art.

Anderson is directed to a method of treating skin wrinkles. His primary teaching relates to treatment with a single wavelength generated by a laser system. Anderson briefly mentions that the source could generate “incoherent radiation.” When discussing treatment parameters, he suggests that the beam has “a wavelength” between 1.3 and 1.8 microns. As noted by Dr. Alexiades, one skilled in the art would understand that Anderson is suggesting treatment with a single wavelength within this range. (Alexiades Declaration ¶11) In particular, Anderson gives examples of various laser systems that can generate light that emits a wavelength in this range. Taken as a whole, the Anderson disclosure teaches the use of a single wavelength treatment and does not suggest a treatment method using broadband light. As noted by Dr. Alexiadis: “The mere reference in the specification that the light source used to generate the desired wavelength could be an incoherent source is ambiguous since the output of an incoherent source can be filtered to generate narrowband light. I note that the concept of treatment with broadband of radiation does not appear in Anderson disclosure. In my view, Anderson fails to teach treating tissue with broadband radiation having a range of 1050 to 1850nm.” (Alexiades Declaration ¶11)

Altshuler ‘042 relates to treating tissue with optical radiation. Altshuler ‘042 discusses using a broad spectrum lamp for treatment. In paragraph [0093], Altshuler ‘042 discusses some preferred wavelength ranges, specifically, between 800 and 1800nm, between 900 and 1400nm and between 1100nm and 1250nm. None of these ranges mentioned in Altshuler ‘042 corresponds to a range covering 1050nm to 1850nm, as recited in claim 15.

As noted by Dr. Alexiades: “The claimed restriction to a wavelength range of 1050 to 1850nm is important because if one utilized the wavelength ranges specified by Altshuler, the depth of penetration and skin tightening results observed with Titan would have been unlikely to be achieved. Wavelengths spanning 800-1000 nm result in much vascular and pigment absorption, limiting the fluence and number of passes one can safely administer, and thereby preventing adequate heat deposition into deeper dermis. The 900 to 1400 nm range would likely result in

similar complications and side effects as aforementioned and allow only superficial dermal injury. Finally, the 1100-1250 nm range would also result in only superficial dermal thermal injury and possibly little skin tightening, if any. Thus, it is my belief that none of the three ranges specified by Altshuler '042 would work in a manner similar to the claimed 1050 to 1800nm range. In my opinion as one skilled in the art, I would not have been motivated to develop a skin tightening method that utilized broadband radiation having a range between 1050 to 1800nm range based on the teachings in Altshuler '042 either alone or in combination with the teachings in Anderson.” (Alexiades Declaration ¶11)

In the Office Action, the Examiner pointed out that Altshuler '042 discloses irradiation times from approximately 2 seconds to approximately 2 hours. The Examiner states that these treatment times overlap the claimed treatment times and “one skilled in the art would use a time appropriate to achieve the desired temperature based on the operating parameters of the radiation source.” Applicants disagree. As noted by Dr. Alexiadis: “Perhaps one of the least obvious aspects of the claimed method relates to the determination of the optimal irradiation time. The claimed 1.2 to 5 second treatment time has done much to contribute to our knowledge in determining optimal time-at-temperature parameters that are necessary to induce neocollagenesis and ne elastogenesis. In my opinion, the claimed 1.2 to 5 second treatment time would not have been obvious in view of the long treatment time (2 second to 2 hours) suggested by Altshuler '042 nor would it have been generally obvious to one skilled in the art.”

Altshuler '780 also relates to treating tissue with optical radiation. The bulk of the disclosure in Altshuler '780 is directed to hair removal. Altshuler '780 includes a few paragraphs (beginning at paragraph [0088]) which discuss skin rejuvenation. For skin rejuvenation, Altshuler suggests treatment with broadband light having the wavelength range illustrated in Figure 7c. The range of wavelengths shown in Figure 7c spans from just about 900nm to 2.5 microns. As noted by Dr. Alexiadis: “It is my opinion that a method for skin tightening which treated tissue with broadband light having a range of 1050 to 1800nm would not be obvious in view of the teachings of Altshuler '780 either alone or in combination with either Anderson or Altshuler '042. Skin tightening targets the deep levels of dermis. In my view, a range of wavelengths spanning 900 nm to 2.5 would be problematic both due to vascular and pigment absorption and on the other end of the

spectrum, possible penetration to adipose tissue. Once again, the claimed restriction to 1050 to 1800 nm wavelength range has in retrospect been shown to be ideal in thermal injury restricted to dermis and extending into deep dermis, without the problems of epidermal, vascular or fatty injury.”

In summary it is respectfully submitted that the subject matter of claim 15 is not obvious to one skilled in the art based on a combination of the references cited by the Examiner. This conclusion is fully support by the Declaration of Dr. Alexiades, someone quite skilled in the art of skin tightening.

In the Office Action, the Examiner cited the patent to Fullmer (5,885,274) against claim 40 which relates to pulsed operation. With respect to claim 15, Fullmer suggests using light having a range of 850 to 1800nm in order to modify collagen. As noted by Dr. Alexiades, a system operated with this wavelength range would produce too much pigment absorption below 1050nm that “would greatly limit the power output and number of passes that could safely be employed, and resulting in little if any skin tightening.” (Alexiades Declaration ¶16)

In the Office Action, the Examiner cited the publication to Vaynberg (2005/0107850) against claim 41 which relates to a method of controlling the lamp. Vanyberg teaches that his lamp can generate an output between 300 and 1100nm [0016]. Paragraph [0031] suggests using a treatment pulse having a wavelength range of 400 to 600nm. Paragraph [0035] discusses how the spectral output of the lamp can be varied by varying the current supplied to the lamp. Figure 4A, 4B and 4C illustrate different spectral distributions that can be achieved by varying the lamp current. All three output spectra have significant portions below 1050nm. None of these ranges is close to the claimed range of 1050nm to 1850nm.

Based on the above arguments and in conjunction with the information provided in the Alexiades Declaration, it is respectfully submitted that independent claim 15 defines patentable subject matter and allowance thereof, along with the claim depending therefrom is respectfully solicited.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, Applicants petition for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in

connection with the filing of this document to **Deposit Account No. 03-1952** referencing **Docket No. 658312001000**. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

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Respectfully submitted,

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